FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

KEVIN CLARK, and WILLIE MAE WILBURN, individually, and on behalf of all others similarly situated, Plaintiffs, v. ACTAVIS GROUP hf, ACTAVIS TOTOWA, LLC (formerly known as Amide Pharmaceutical, Inc.), ACTAVIS INC., ACTAVIS ELIZABETH, LLC, ACTAVIS US, MYLAN, INC., MYLAN PHARMACEUTICALS, INC., MYLAN LABORATORIES, INC., MYLAN BERTEK PHARMACEUTICALS, INC., and UDL LABORATORIES, INC., Defendants.	Civil Action No. 08-2293 (JAG) **OPINION**

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GREENAWAY, JR., U.S.D.J.

This matter comes before this Court on the motion of Plaintiffs Kevin Clark and Willie Mae Wilburn (collectively "Plaintiffs"), individually and on behalf of all others similarly situated, for an order to show cause, requesting that: (1) Defendants Actavis Group hf, Actavis Totowa, LLC, Actavis Inc., Actavis Elizabeth, LLC, Actavis US, Mylan, Inc., Mylan Pharmaceuticals, Inc., Mylan Laboratories, Inc., Mylan Bertek Pharmaceuticals, Inc., and UDL Laboratories, Inc. (collectively "Defendants") provide urgent notice to unnamed class members and physicians; (2) this Court grant Plaintiffs' request for injunctive relief requiring Defendants to preserve evidence; and (3) this Court order the appointment of temporary interim class counsel.[1] For the reasons set forth below, Plaintiffs' motion is denied.

[1] This matter also comes before this Court on Defendants' motion to stay this case pending the decision of the Judicial Panel on Multidistrict Litigation regarding whether this matter shall be transferred to a multidistrict litigation court. As a result of this Court's resolution of Plaintiffs' motion, this Court need not reach the merits of Defendants' motion. Therefore,

I. BACKGROUND

"On . . . April 25, 2008, the United States Food and Drug Administration ("FDA") announced a Class I Recall[2] of all lots of Bertek and UDL Laboratories Digitek®[3]." (Compl. ¶ 50.) Plaintiffs, on May 9, 2008, filed this lawsuit against Defendants for

> design, manufacturing, producing, supplying, inadequately inspecting, testing, selling and distributing dangerous, defective, misbranded and adulterated Digitek® (digoxin tablets, USP) . . . containing an amount of the drug's active ingredient, digoxin, exceeding the dose set forth on the label and in some cases exceeding the dose approved for medical treatment in humans.[4]

(Compl. ¶ 1.)[5]

Defendants' motion is denied, as moot.

[2] "Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. [A] Class I [R]ecall [is] a situation in which there is reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death." U.S. Food and Drug Administration, Recalls: Background and Definitions, http://www.fda.gov/oc/po/firmrecalls/recall_defin.html (last visited July 21, 2008). The "FDA's role under the guidelines [governing product recalls] is to monitor company recalls and assess the adequacy of a firm's action. After a recall is completed, FDA makes sure that the product is destroyed or suitably reconditioned[,] and investigates why the product was defective." U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, FDA/CFSAN FDA Recall Policies, http://vm.cfsan.fda.gov/~lrd/recall2.html (last visited July 21, 2008).

[3] "Digitek® is the brand-name of one of the cardiac glycosides, a closely related group of drugs having in common specific effects on the myocardium of the heart." (Compl. ¶ 23.)

[4] Specifically, Plaintiffs claim: negligence, *res ipsa loquitor*, negligence per se, defective design, manufacturing defect, failure to warn, strict products liability, breach of express and implied warranties, misrepresentation and suppression, fraud, negligent misrepresentation, violations of the New Jersey Consumer Fraud Act, medical monitoring, and unjust enrichment. (See generally Compl.)

[5] Plaintiffs have since filed a First Amended Complaint, (see generally First Am. Compl.); however, this Court will rely on the allegations of the Complaint to resolve the present motion.

On June 3, 2008, Plaintiffs filed an emergency order to show cause[6]

> seek[ing] notice to the class, and to physicians that prescribed digoxin, on an emergent basis to protect the health and avoid further damage from occurring;
>
> request[ing] that the undersigned counsel be appointed temporary interim Class Counsel for the narrow purposes of implementing the notice;
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> seek[ing] an order requiring Defendants to cease and desist all efforts inducing consumers to return to Defendants, rather than preserving the drug and packaging themselves; and, an order requiring Defendants to preserve all Digitek® tablets and[/]or other items returned by consumers as part of the recall.

(Mem. in Supp. of Order to Show Cause and Emergency Mot. Requesting Defs. to Provide Prompt and Urgent Notice to Unnamed Class Members and Physicians, for Injunctive Relief to Preserve Evidence and Mot. of Counsel to be Appointed Temporary Class Counsel ("Pls.' Mot.") 4.)

Defendants argue that "Plaintiffs' request for injunctive relief improperly seeks to invade the province of the FDA in regulating product recalls[,]" and that the FDA has primary jurisdiction over all issues raised in Plaintiffs' motion. (Br. in Opp'n to Pls.' Req. for Order to Show Cause and Mot. Requesting Defs. to Provide Prompt and Urgent Notice to Unnamed Class

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[6] Plaintiffs' motion appears to request injunctive relief and, in fact, is entitled "Motion . . . Requesting Injunctive Relief . . . . " (See generally Pls.' Mot.) However, Plaintiffs claim, in their reply brief, that they "are not seeking injunctive relief." (Pls.' Resp. to Defs.' Opp'n 12.) In an attempt to clarify the relief sought, this Court asked Plaintiffs' counsel, at oral argument, "So your only issue is the breadth of dissemination?" (Order to Show Cause Hr'g Tr. ("Tr.") 9:11-12, July 14, 2008.) Plaintiffs' counsel stated, "Yes. Get out the label and save the product, yes." (Tr. 9:12-14.) However, and after many contradictory statements by Plaintiffs' counsel as discussed infra Section III, this Court construes Plaintiffs' request as one for an order requiring Defendants to issue an additional notice, containing more information provided in the Digitek® label, to Digitek® consumers and pharmacies that distribute Digitek®. (Tr. 18:19-24 (THE COURT: "Now, while this has been described by Mr. Levin as the breadth of dissemination . . . the issue is really that the warnings disseminated by pharmacies to their consumers are inconsistent and that the results of toxicity studies, et cetera, should be disseminated."); see also Tr. 24:8-19; 28:21-25.)

Members and Physicians, for Injunctive Relief to Preserve Evidence and Mot. of Counsel to be Appointed Temporary Class Counsel ("Defs.' Opp'n") 2-3.)

This Court heard oral argument on the pending motion on July 14, 2008.

II. LEGAL STANDARD[7]

The doctrine of primary jurisdiction is a firmly established principle which provides that

> in cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion, agencies created by Congress for regulating the subject matter should not be passed over. . . . Uniformity and consistency in the regulation of business entrusted to a particular agency are secured, and the limited functions of review by the judiciary are more rationally exercised, by preliminary resort for ascertaining and interpreting the circumstances underlying legal issues to agencies that are better equipped than courts by specialization, by insight gained through experience, and by more flexible procedure.

IPCO Safety Corp. v. WorldCom, Inc., 944 F. Supp. 352, 355 (D.N.J. 1996) (quoting Unimat, Inc. v. MCI Telecomms. Corp., No. 92-5941, 1992 U.S. Dist. LEXIS 19320, at *2 (E.D. Pa. Dec. 16, 1992)); see also Bernhardt v. Pfizer, Inc., No. 00-4042, 2000 WL 1738645, at *2 (S.D.N.Y. Nov. 22, 2000) (citing Nat'l Commc'ns. Assoc. v. Am. Tel. & Tel. Co., 46 F.3d 220, 222-23 (2d Cir. 1995) (internal citations omitted) ("the doctrine of primary jurisdiction allows a federal court to refer a matter extending beyond the 'conventional experiences of judges' or 'falling within the realm of administrative discretion' to an administrative agency with more specialized experience, expertise, and insight. Specifically, courts apply primary jurisdiction to cases involving technical and intricate questions of fact and policy that Congress has assigned to a specific agency.")).

"Primary jurisdiction applies when decision-making is divided between courts and

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[7] As discussed infra Section III, this Court does not have jurisdiction over regulatory matters under the FDA's authority, pursuant to the primary jurisdiction doctrine. Therefore, this Court need not resolve Plaintiffs' motion by analyzing the law governing injunctive remedies.

administrative agencies. It calls for 'judicial abstention in cases where protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme.'" Cheyney State Coll. Faculty v. Hufstedler, 703 F.2d 732, 736 (3d Cir. 1983) (quoting United States v. Phila. Nat'l Bank, 374 U.S. 321, 353 (1963)). "Essentially, the doctrine creates a workable relationship between the courts and administrative agencies []," MCI Telecomms. Corp. v. Teleconcepts, Inc., 71 F.3d 1086, 1105 (3d Cir. 1995) (internal citation omitted), and may even be applied "in cases where the questions raised 'are within the ordinary experience of [the] judiciary.'" IPCO Safety Corp., 944 F. Supp. at 355 (internal citation omitted); see also In re Human Tissue Prods. Liab., 488 F. Supp. 2d 430, 432 (D.N.J. 2007) (Martini, J.) (citing United States v. W.P.R. Co., 352 U.S. 59, 63 (1956) ("Under the doctrine of 'primary jurisdiction,' when an activity is arguably subject to an administrative agency's expertise, such as the FDA, federal courts must defer to the exclusive competence of that agency.")).

To determine whether the doctrine of primary jurisdiction is applicable, a court must consider:

> (1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise;
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> (2) whether the question at issue is particularly within the agency's discretion;
>
> (3) whether there exists a substantial danger of inconsistent rulings; and
>
> (4) whether a prior application to the agency has been made.

IPCO Safety Corp., 944 F. Supp. at 356 (quotation omitted).

III. DISCUSSION

Plaintiffs argue that the doctrine of primary jurisdiction does not apply to the case sub

judice because "[t]he notice that Plaintiffs seek does not raise an issue of fact outside the ambit of conventional judicial experience[, and p]reserving evidence[] is exclusively within the ambit of the Court, not the FDA." (Pls.' Resp. to Defs.' Opp'n 6.) Plaintiffs claim that this Court is relieved from engaging in any medical or technical analyses because the FDA-approved Digitek® label contains the requested information. (Tr. 47:17-49:12.)[8]

Defendants, on the other hand, rely on In re Human Tissue Products Liability Litigation, 488 F. Supp. 2d 430 (D.N.J. 2007), and Bernhardt v. Pfizer, No. 00-4042, 2000 WL 1738645 (S.D.N.Y. Nov. 22, 2000), and argue that this Court would have to conduct extensive medical and policy analyses to determine the content of any additional notice sent to consumers and pharmacies, particularly, because the FDA has placed its imprimatur on the recall notice already disseminated. When asked by this Court whether reprinting information included in the Digitek® label in the proposed notice would require this Court to engage in any medical analysis, Defendants responded,

> MR. DEAN: Yeah, there's a lot of medical determinations made in - - that you would have to make to determine whether that is indeed an appropriate risk communication to this group.
>
> Just because it's in the label it doesn't mean it's [an] appropriate risk determination

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[8] MR. WEINKOWITZ: . . . You don't have to make a scientific determination. We give you the label. . . .

. . . .

THE COURT: So, I understand your position that I don't have to engage in any medical or policy considerations that are left to an administrative agency because there's - - in the first instance, there's no dispute between the parties, and this is purely lifted from the label.

(Tr. 47:21-48:24.)

as to the issues confronting this group.

(Tr. 51:10-16; see also Tr. 31:19-33:8.)

Plaintiffs attempt to distinguish Human Tissue and Bernhardt;[9] however, this Court believes that these cases share a common issue with the present matter - - what is the appropriate dissemination of medical information to the consuming public? In Human Tissue, the plaintiffs filed a motion requesting urgent notice be sent to unnamed class members based on the same principles as the motion now before this Court. 488 F. Supp. 2d at 431. They claimed, as Plaintiffs state here, that an additional notice was required because inconsistencies existed in the notification methods approved by the FDA in connection with its recall of unscreened human tissue. Id. The plaintiffs argued that the court "possesse[d] the authority to order this notice under its 'inherent powers' and its ability to manage complex multidistrict litigation." Id. at 432. The court rejected the plaintiffs' position, and held that the doctrine of primary jurisdiction applied because the court did not have the expertise to determine "when notice is required, what the notice should contain, and who the notice should be sent to." Id. at 433. The court stated that "the issue of providing notice to unnamed class members is a decision best left to the Food and Drug Administration . . . ." Id. at 432.

Similarly, in Bernhardt, the plaintiffs sought "mandatory injunctive relief in the form of an emergency notice sent to Cardura users and their physicians." 2000 WL 1738645, at *1. The

[9] Plaintiffs state that this case differs both from Human Tissue and Bernhardt because Plaintiffs do not request this Court to determine the scientific veracity of an FDA, or other medical, opinion relating to Digitek®. (Tr. 8:23-9:3; see also Tr. 41:8-20.) Instead, Plaintiffs argue that because the FDA has already released some information found in the Digitek® label, regarding potential harms, ordering more information from the label to be included in an additional notice sent to consumers and pharmacies will not invade the province of the FDA. (Id.)

plaintiffs requested that notice be sent to inform the consumers and physicians about a medical study that stated that Cardura was "less effective in preventing heart failure compared to a widely used diuretic drug . . . ." Id. The court, holding that the doctrine of primary jurisdiction applied, refused to send the notice, and stayed the case pending resolution of the issue by the FDA. Id. at *3.

This Court agrees with the holdings in Human Tissue and Bernhardt, and finds that the primary jurisdiction doctrine applies to this case for a number of reasons. First, Congress vested the FDA with the authority to monitor and supervise product recalls. In re Human Tissue Prods. Liab., 488 F. Supp. 2d at 432 (citing 21 C.F.R. § 7.40(a)). "These regulations set forth specific recall procedures whereby the FDA assumes control over monitoring recalls and assesses the adequacy of a firm's efforts in undertaking the recall." Id. (citing 21 C.F.R. §§ 7.40-7.59). Specifically, an ad hoc committee of FDA scientists evaluates health hazards associated with the product being recalled, and then determines the classification to assign to the recall. See 21 C.F.R. §§ 7.41(a)-(b) (2008).

In collaboration with the recalling firm, the FDA "review[s] the adequacy of a proposed recall strategy developed by a recalling firm and recommend[s] changes as appropriate." Id. § 7.42(a)(2); see also id. § 7.46(b) (stating that the FDA "will review the information submitted, advise the firm of the assigned recall classification, recommend any appropriate changes in the firm's strategy for the recall, and advise the firm that its recall will be placed in the weekly FDA Enforcement Report.").

> As these regulations show, Congress clearly vested the FDA with the regulatory authority to assess and manage the [recall, and the] communications regarding product recalls. Implicit in this authority is the understanding that the FDA possesses

> the necessary expertise to determine when notice is required, what the notice should contain, and who the notice should be sent to. By requesting the Court to issue a similar notice here, Plaintiffs are essentially asking the Court to perform the tasks traditionally relegated to the FDA.

In re Human Tissue Prods. Liab., 488 F. Supp. 2d at 433; see also 21 C.F.R. §§ 7.40, 7.42, 7.46, 7.49.

Second, determining the necessity of an additional notice requires this Court to engage in the type of technical analysis conducted by the FDA. Plaintiffs argue that this Court could refrain from conducting any medical analysis by including in the new notice only information taken verbatim from the Digitek® label. However, any consideration and subsequent determination that: 1) the original notice is inadequate; 2) another notice is necessary; and 3) the information contained in the Digitek® label is sufficient to remedy the deficiencies in the original notice, by definition requires some understanding, deciphering, and decision-making regarding the FDA's prior determination of the content of the recall notice.[10] In particular, this Court would have to consider the medical hazards associated with the ingestion of Digitek® containing an increased dosage of the active ingredient, digoxin. See 21 C.F.R. § 7.49(a) ("The format, content, and extent of a recall communication should be commensurate with the hazard

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[10] "On April 24, 2008, Actavis conferred with the Recall Coordinator at the [FDA] District Office in New Jersey . . . regarding a recall strategy for Digitek®." (Defs.' Opp'n 6.) The FDA approved Actavis' recall strategy on April 25, 2008, but requested that certain modifications be made in the press release and notice. (Id.) "Actavis incorporated [the] FDA's changes and [the] FDA approved the final press release and notice." (Id.) (citing Decl. of Misbah Sherwani ("Sherwani Decl.") ¶ 6; Decl. of Cassandra Bird ("Bird Decl.") ¶ 4.)

Actavis then sent the "final FDA-approved recall notice and press release to its distributor, Mylan." (Id. at 7 (citing Sherwani Decl. ¶ 7; Bird Decl. ¶ 3).) "Mylan sent a draft recall notification for Digitek® to [the] FDA on April 28, 2008," and the FDA approved it on the same day. (Id. (citing Bird Decl. ¶ 5).) Mylan sent the approved notice to Stericycle, Inc., which is charged with overseeing the notice sent to pharmacies. (Id.)

of the product being recalled and the strategy developed for that recall."). This Court also would be required to determine which information regarding potential hazards must be included in the notice, and which information detracts from the message. See id. § 7.49(c)(2) ("The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message."). This Court does not have the expertise to conduct such an intense medical analysis. This responsibility clearly lies within the realm of the FDA's authority.[11] See id. § 7.41(a).

The same is true of the recall procedures. Plaintiffs argue that the preservation of evidence is exclusively within this Court's authority. (Pls.' Resp. to Defs.' Opp'n 6.) However, Plaintiffs fail to realize that the relief they seek would interfere with the FDA's recall. Specifically, Plaintiffs request that this Court order "Defendants to cease and desist all efforts inducing consumers to return [their remaining Digitek® tablets] to Defendants, rather than preserving the drug and packaging themselves; and . . . to preserve all Digitek® tablets and[/]or other items returned by consumers as part of the recall." (Pls.' Mot. 4.) As Defendants aptly note, "[t]he FDA regulates procedures for the FDA to monitor recalls and assess the adequacy of a firm's efforts in recall." (Defs.' Opp'n 3 (citing 21 C.F.R. § 7.40(a)).) If this Court were to grant Plaintiffs' motion, and order Defendants to leave the Digitek® tablets in the hands of

[11] The United States, appearing as amicus curiae in support of Defendants, agrees. See FED. R. APP. P. 29(a) ("The United States or its officer or agency, or a State, Territory, Commonwealth, or the District of Columbia may file an amicus-curiae brief without the consent of the parties or leave of court."). It states that the "FDA continues its monitoring of this recall and other efforts to assure full regulatory compliance and resolution of all aspects of the violations identified in [its] investigation. [The] FDA does not have any information that would indicate that another notice at this time would add any benefit to the public health, and is concerned that it might confuse patients and potentially lead to adverse consequences." (Br. for U.S. as Amicus Curiae Supporting Defs. at 2-3.)

consumers, the very people for whom Plaintiffs express profound concern, this order would directly interfere with the FDA's recall.

Third, Plaintiffs have provided no contrary legal support.[12] In fact, Plaintiffs concede that in order to determine that a new notice is required, medical expert testimony is necessary.[13]

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[12] Plaintiffs' reliance on Jaffe v. United States, 592 F.2d 712 (3d Cir. 1979) is misguided. In Jaffe, the plaintiffs requested that notice be sent to members of the United States Army who may have been exposed to nuclear radiation as a result of the United States' nuclear testing in 1953. 592 F.2d at 714. The case concerns the doctrine of sovereign immunity, id. at 715, rather than the doctrine of primary jurisdiction. No recalls had been effectuated, and no procedures had been developed to notify servicemen of the potential hazards of radiation exposure. Id. at 720. These facts are unlike those before this Court. Here, notice has been sent, and the FDA is actively overseeing the recall of Digitek®. (Compl. ¶ 50.)

[13] THE COURT: . . . If the FDA made a determination about the substance of the release that it approved of, it made that determination, would you agree, in consultation with doctors, experts? . . . .

. . . .

. . . . You would agree with that, right?

MR. LEVIN: Sure.

THE COURT: So doctors . . . working either with or for the FDA, said that the substance of this release is sufficient because it achieves our overall objective of public safety. Right?

Now, you might not agree with the substance of it, but you agree that that's what was thought of when it was constructed and then approved, right?

MR. LEVIN: Yes.

THE COURT: . . . So, someone comes along and says, you know, this release would be more effective if it said, A, B, C. . . . Now, we don't want a lawyer saying that A, B, C, would be better, right? Because that would mean that a lawyer is making a judgment as to what a more effective communique of a medical nature would be between a pharmacist and . . . the ultimate consumer, right?

So, isn't that what you're asking me to do, to make a determination to

Fourth, substantial danger exists if this Court decided to rule in favor of Plaintiffs. "An order from this Court [does] not preclude the FDA from issuing another notice regarding the recall, or requiring Defendants to do so." In re Human Tissue Prods. Liab., 488 F. Supp. 2d at 433. In addition, this Court's order could not, and would not, divest the FDA of its authority to oversee the entire recall of Digitek®. Therefore, it is the FDA, not this Court who has the expertise in modifying the procedures associated with the recall. See 21 C.F.R. § 7.42(2).

Finally, although Plaintiffs have not made a prior application to the FDA (Pls.' Resp. to Defs.' Opp'n 11), this failure is not dispositive. Bernhardt, 2000 WL 1738645, at *3. However, this Court disagrees with Plaintiffs' opinion that seeking redress in the form of a Citizen's Petition, pursuant to 21 C.F.R. § 10.30, will result in undue delay. (Pls.' Resp. to Defs.' Opp'n 11.) Plaintiffs' claims are not dependent on whether this Court issues notice to consumers or physicians, or modifies the procedures of the FDA recall. Bernhardt, 2000 WL 1738645, at *3. If Plaintiffs so choose, they may file a Citizen's Petition with the FDA regarding the appropriateness of the notice and recall procedures.

IV. CONCLUSION

This Court finds that the doctrine of primary jurisdiction is applicable to each of the issues raised in Plaintiffs' motion.[14] Therefore, this Court denies Plaintiffs' motion in its

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> basically pass on what the most effective communique is to the consumer?
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> MR. LEVIN: Well, as phrased in the latter part of your question, the answer is yes."

(Tr. 35:7-36:10.)

[14] Because the doctrine of primary jurisdiction applies to the issues raised in Plaintiffs' motion, there is no need for the other requested relief - - the appointment of temporary interim

entirety. In addition, having resolved Plaintiffs' motion on its merits, this Court finds no reason to address Defendants' motion to stay these proceedings pending a decision by the Judicial Panel on Multidistrict Litigation. For this reason, Defendants' motion to stay is denied, as moot.

Dated: July 25, 2008

S/Joseph A. Greenaway, Jr.
JOSEPH A. GREENAWAY, JR., U.S.D.J.

class counsel.